

### REMARKS

Claims 18-21 and 32-38 are pending in this patent application. Claims 18 and 20 have been amended to include the phrase "capsule-shaped." Support for these amendments may be found throughout the specification, for example, on page 4, lines 12-18. Support for added claims 32-38 may be found throughout the specification, for example, in Example 1 on page 11. Claims 22-31 have been cancelled and claim 38 has been added. Claims 21-31 have been cancelled to pursue the pending method claims and applicants continue to disagree with the rejection of claims 22-31 over the cited references. Claim 38 is the restoration of the subject matter of now cancelled claim 21.

Claims 18-20 stand rejected as allegedly being unpatentable over the combined teachings of the U.S. Patent Nos. 5,248,310 to Barclay (hereinafter "the Barclay patent"), 5,785,994 to Wong (hereinafter "the Wong Patent"), 5,582,838 to Rork *et al.* (hereinafter "the Rork patent") and 5,422,831 to Misra *et al.* (hereinafter "the Misra patent"). In the instant patent application, the Examiner clearly has not made the requisite showing. Initially, the Examiner asserted that "it would have been obvious ... to employ Barclay's method of detecting different layers in the three layer osmotic dosage form of Wong, by incorporating a coloring agent, as shown by Barclay, in any desired layer" (Office Action dated July 14, 2004, at page 3). Applicants, in turn, demonstrated that simply incorporating a coloring agent into the Wong dosage form, as proposed, would not have produced any claimed tablet (*i.e.*, because the Wong dosage form has only one drug-containing layer whereas the claimed tablets have at least two). Although the Examiner now alleges that adding drug layers to the Wong dosage form would have been "well within the ordinary level of a skilled artisan" (Office Action dated March 11, 2005, at page 3), the Examiner has not identified any evidence demonstrating that this further modification of the Wong dosage form would have been one that those of ordinary skill would have been motivated to make. Absent such evidence, the rejection of claims 18-20 for alleged obviousness lacks evidentiary basis and should be withdrawn. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1124-25, 56 USPQ2d 1456, 1459 (Fed. Cir. 2000) ("a showing of a suggestion, teaching, or motivation to combine the prior art references is an 'essential component of an obviousness holding'").

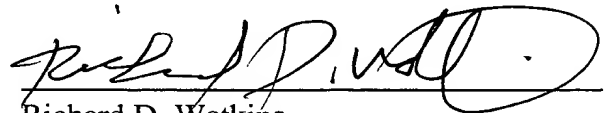
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37 CFR § 1.116

The Examiner has also failed to identify any evidence that those of ordinary skill in the art would have been motivated to modify the references' teachings in a way that would have produced a claimed invention. Although the Examiner (employing the hindsight provided by Applicants' disclosure) asserts that "a coloring agent can be used in determining orientation of a formulation" (Office Action at page 7), there is no evidence that a person of ordinary skill at the time of Applicants' invention actually would have been motivated to modify the disclosed dosage forms in this manner. Even if such evidence *were* of record, the instant rejection would still lack support because the resulting dosage form would have fewer drug-containing layers than the claimed tablets. Accordingly, the Examiner would still need to come forward with evidence that those of ordinary skill would have been motivated to add drug-containing layers to the disclosed dosage forms. Since no such evidence is of record, the rejection for alleged obviousness is improper. *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) ("particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed").

Applicants believe that the foregoing constitutes a complete and full response to the Office Action of record. Applicants respectfully submit that this application is now in condition for allowance. Accordingly, an indication of allowability and a Notice of Allowance are respectfully requested.

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